DOCKET NO.: ALLE0041-100 **PATENT**
(17672 BOT)
Serial No. 10/814,764

REMARKS

Upon entry of this amendment, claims 1-11 and 13-19 will be pending. Amended claims 1, 6, 7 and 13 are fully supported by the specification at, for example, page 23, lines 14-19). Claim 12 has been canceled as it is identical to claim 7. New claims 15-19 are fully supported by the specification at, for example, page 23, lines 14-18, and the original claims 2-5. The new claims recite that the pressure sore is not related to contractures or spasticity. No new matter is added.

The Claims Are Fully Described

Claims 1-14 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking written description with respect to the term "substantially". The amended claims now recite that a botulinum toxin is administered to the pressure sore or to the vicinity of the pressure sore "without reducing spasticity of a muscle". This feature is fully described in the specification at, for example, page 23, lines 14-18.

The Claims Are Definite

Claims 1-14 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite with respect to the term "substantially". This rejection is rendered moot, as the term "substantially" is deleted from the claims.

The Claims Are Novel

Prior to discussing the novelty of the claims over the cited prior references, it is important to understand the basis of Applicant's claimed invention, and how it is significantly different from the cited prior references.

A pressure sore of the present invention is associated with prolonged pressure applied to the skin (the specification at page 1, lines 15-16). A botulinum toxin

administered to the ulcerative area of the pressure sore (in accordance with the present invention) can "inhibit the release of new blood vessel production mediators..., and decrease the recruitment of new blood vessels at the site of a pressure sore and thereby decrease the development of the pressure sore" (the Specification at page 27, lines 9-13).

The cited prior references do not anticipate the claimed invention because the references do not teach an administration of a botulinum toxin to or to a vicinity of the pressure sore where the botulinum toxin

- can inhibit the release of new blood vessel production mediators and decrease the recruitment of new blood vessels at the site of a pressure sore, and
- does not cause a reduction in contracture or spasticity of a muscle.

The cited prior references either do not teach the administration of a botulinum toxin for treating pressure sore, or they teach that the botulinum toxin is administered to cause reduction in contracture or spasticity of a muscle (as the muscle spasm causes abrasion which can lead to pressure sore). Further, the prior references do not teach the administration to a pressure sore or to a vicinity of a pressure sore. Instead, as previously mentioned, the prior references teach the administration to a muscle to cause a reduction of contracture or spasticity of that muscle.

The Pohl Reference

Claims 1-4, 6-10 and 12-13 are rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Pohl et al. (Arch Phys Med Rehabil, 83:35-39, hereinafter "the Pohl reference"). The Pohl reference teaches that an ulcer caused by severe spasticity can be treated with serial castings. The serial casting functions to immobilize the spastic muscle that causes abrasion (and thus pressure sore/ulcer). Further, the Pohl reference teaches that the spasticity of the muscle can be further reduced by administering a botulinum

toxin. For example, the Pohl reference teaches that a botulinum toxin can be administered at a "motor point under electrophysiologic monitoring" to reduce spasticity (the Pohl reference, page 37, first column).

Since the Pohl reference teaches the use of a botulinum toxin to reduce spasticity of a muscle, and the claimed invention specifically recites that the administered botulinum toxin does not cause reduction in spasticity, the Pohl reference cannot anticipate the claims.

The Kennedy Reference

Claims 1-3, 6-9, 12 and 14 are rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Kennedy (Wisconsin Medical Journal, 1997 United States, vol 96, no. 12, page 21-23, hereinafter "the Kennedy reference"). Similar to the Pohl reference, the Kennedy reference teaches that a botulinum toxin can be administered to reduce spasticity of a muscle, and thereby treating the pressure sore (the Kennedy reference, page 22, columns 2-3). However, the claimed invention specifically recites that the administered botulinum toxin does not cause reduction in spasticity. Thus, the Kennedy reference cannot anticipate the claims.

The Gassner Reference

Claims 1-12 are rejected under 35 U.S.C. 102(b) for allegedly being anticipated by U.S. Patent 6,447,787 (hereinafter "the Gassner reference"). The Office Action admits that the Gassner reference does not teach the administration of a botulinum toxin to treat pressure sore. Instead the Gassner reference teaches the administration of a botulinum toxin to enhance wound healing. Further, the "wounds" of the Gassner reference are not associated with a pressure sore, but are associated with lacerations and bone fracture (the Gassner reference, col. 3, lines 5-36). (the Office Action, page 5). However, the Office Action alleges that the claims are inherently anticipated by the

Gassner reference because the reference discloses the administration of a botulinum toxin at a dose that overlaps that of the claimed invention.

It is important that the Office recognizes that a reference can only inherently anticipate the claims if the reference discloses *all* of the features of the claims (explicitly or inherently). That is,

> [t]o establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

(MPEP at 2112 IV, emphasis added). The present claims recite a method of treating a pressure sore in a patient. Thus, a feature of the claims include a patient having pressure sore. The Gassner reference is silent with respect to the treatment of a patient having pressure sore. In fact, a patient having pressure sore is not "necessarily present" in the Gassner reference, as the Gassner reference only describes a method for treating wound pain.

Since the Gassner reference does not disclose all the features of the claimed invention (e.g., a patient having pressure sore), the Gassner reference cannot anticipate the claimed invention.

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In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,

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